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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,253	11/26/2003	James Samsoondar	213202.00487	6103

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/721,253	<b>Applicant(s)</b> SAMSOONDAR, JAMES	
	<b>Examiner</b> Maureen M. Wallenhorst	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-44, 52-66 and 97 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-44, 52-66 and 97 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/26/03</u> . | 6) <input type="checkbox"/> Other: _____  |

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1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Canada (PCT/CA97/00418) on July 12, 1997, and the United Kingdom on June 12, 1996. It is noted, however, that applicant has not filed a certified copy of the PCT and English application as required by 35 U.S.C. 119(b).

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: It fails to claim priority under 35 USC 119 to PCT application serial number PCT/CA97/00418.

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprising" and "comprises". In addition, the abstract is too long. Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: In paragraph number 1 on page 1 of the specification, the phrase – now US Patent no. 6,828,152 issued on December 7, 2004—should be inserted after the phrase "US serial number 10/023,869, filed December 21, 2001", and the phrase –now US Patent no. 6,372,503 issued on April 16, 2002—should be

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inserted after the phrase “US serial number 09/147,373, filed December 11, 1998” so as to update the status of these applications. Please note that the filing date of application serial no. 09/147,373 is not June 12, 1998, but rather December 11, 1998.

Appropriate correction is required.

6. Claims 4, 11, 12, 13, 17, 23, 28, 32, 36, 41, 54, 55, 62, 66 and 97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, the full meanings for the abbreviations “total Hb, oxy-Hb and total Hb minus met-Hb” should be recited. This same change should also be made in claims 11, 12, 13, 23, 28, 36, 41, 54 and 62.

Claims 12-13 are indefinite since these claims recite various different substances that may be contained in the quality control material. However, since these claims depend from claims 9 and 10 that recite that the quality control material must contain a substance that mimics turbidity or a perfluorocarbon-like blood substitute, claims 12-13 should recite that the quality control material contains therein one or more substances in addition to a substance that mimics turbidity and a perfluorocarbon-like blood substitute.

In claim 17, the full meanings for the abbreviations “PVP” and “PEG” should be recited. This same change should also be made in claims 32 and 66.

Claim 55 is indefinite since it recites that the analytes in the quality control material are whole blood, serum, plasma, etc. However, these materials are body fluids in which the analytes are found, not the analytes themselves.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 52-62 and 97 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-9 of U.S. Patent No.

6,828,152. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a quality control material comprising one or more substances that exhibit an absorbance spectrum characterized as having a negative slope for a continuous spectral segment of about 5 to about 400 nm in length, wherein the one or more substances mimic one or more analytes found in a sample such as plasma, serum, synovial fluid, cerebrospinal fluid, urine, feces, etc., and wherein the one or more analytes include an indicator of hemolysis such as total Hb, oxy-Hb or total Hb minus met-Hb, bilirubin, biliverdin, methylene blue, a simulator of turbidity, etc.

9. Claims 1-44, 52-66 and 97 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 13-21, 24-37 and 40-56 of copending Application No. 10/319,492. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a method of monitoring a spectrophotometric apparatus comprising one or more than one calibration algorithm for one or more than one analyte, a reagentless method for determining the

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concentration of one or more than one analyte in the spectrophotometric apparatus, a method of selecting one or more than one substance as a quality control material for monitoring the one or more calibration algorithms on the spectrophotometric apparatus, and a quality control material for monitoring the calibration algorithms on the spectrophotometric apparatus that comprise essentially the same steps and components therein. The only difference between the sets of claims is that claims 1-44, 52-66 and 97 of the instant application recite that the quality control spectral segment having a negative slope of about 5-400 nm in length includes the principal calibration wavelengths for the one or more than one analyte whereas claims 1-10, 13-21, 24-37 and 40-56 of application serial no. 10/319,492 recite that the quality control spectral segment having a negative slope of about 5-400 nm in length overlaps an observed analyte spectral segment for one or more than one analyte. It would have been obvious to one of ordinary skill in the art to realize that if the quality control spectral segment includes the principal calibration wavelengths for the one or more than one analyte, then the quality control spectral segment must inherently overlap an observed analyte spectral segment, at least in the region of the principal calibration wavelengths.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of : Samsoundar (US Patent 6, 372, 503), which corresponds to parent application serial no. 09/147,373.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst  
Primary Examiner  
Art Unit 1743

mmw

December 12, 2005

*Maureen M. Wallenhorst*  
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